



UNITED STATES DEPARTMENT OF COMMERCE
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08/846,017

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/846,017	04/25/97	CECH	

HM21/0928

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100-07824
EXAMINER

SCHERTZ, J. T. PAPER NUMBER 15

1642
DATE MAILED: 09/28/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 3/2/98
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-26 is/are pending in the application.
- Of the above, claim(s) 18-20 is/are withdrawn from consideration.
- ☒ Claim(s) 6-12 and 21-26 is/are allowed. allow
- ☒ Claim(s) 1-5 and 14-17 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number)
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892 - 2 sheets
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 6 sheets
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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DETAILED ACTION

Claims 21-26 were added by the preliminary amendment filed March 2, 1998, claims 1-26 are pending in the application.

Election/Restriction

Applicant's election of Group I, claims 1-17 and 21-26 is acknowledged; claims 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse.

Claim Rejections - 35 USC § 112, second paragraph

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

SEQ ID NO:83 is recited twice in claim 1; is some other SEQ ID NO intended?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 2-4, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Glaser *et al.* (Molecular Microbiology, vol. 10, pp. 371-384, 1993) **or** Natarajan *et al.* (PNAS, vol. 89, pp. 8874-8878, 1992) **or** Du *et al.* (Direct submission to GenBank, accession no. S53396, 1995).

Claim 2 is directed to a polynucleotide encoding a polypeptide **comprising** the amino acid sequence selected from the group consisting of SEQ ID Nos:71, 73, 77 and 83, among several others. No upper size limit is specified for the peptides. Claim 3 is directed to polynucleotides which would hybridize specifically to telomerase sequences; claim 4 is directed to complements of sequences encoding the instant peptides. Claim 15 recites that the polynucleotide is contained on a recombinant vector; claim 16 recites that it is in a host cell.

Glaser *et al.* disclose a nucleic acid sequence encoding a peptide containing the instant SEQ ID NO:71 (the relevant nucleic acid sequence was submitted to GenBank under accession no. S39696).

Natarajan *et al.* disclose a nucleic acid sequence encoding a peptide containing the instant SEQ ID NO:73 (the relevant nucleic acid sequence was submitted to GenBank under accession no. A46242).

Du *et al.* disclose a nucleic acid sequence which encodes a peptide containing the instant SEQ ID Nos:77 and 83 (the relevant nucleic acid sequences were submitted to GenBank under accession nos. S53396 and Q06163).

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Claim 5 is rejected under 35 U.S.C. 102(a) as being anticipated by Zahner *et al.* (Direct submission to GenBank, accession no. L38903, available July 26, 1996).

Claim 5 is directed to a polynucleotide sequence that hybridizes under stringent conditions to a nucleic acid sequence selected from the group consisting of SEQ ID NO:66, among others.

Zahner *et al.* disclose a nucleic acid sequence identical to SEQ ID NO:66 over a span of approximately 500 residues; Zahner *et al.*'s polynucleotide would hybridize under stringent conditions to SEQ ID NO:66.

Claims 13 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier *et al.* (direct submission to Gen Bank, EST database, accession no. W70315, available October 17, 1996).

Claim 13 is directed to an antisense molecule "complementary to at least a portion of the nucleotide of SEQ ID NO:100." Claim 14 recites that the antisense molecule is in a pharmaceutical excipient.

Hillier *et al.* disclose a polynucleotide (accession no. W70315) which is complementary to a portion of SEQ ID NO:100.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

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commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glaser *et al.* (Molecular Microbiology, vol. 10, pp. 371-384, 1993) **or** Natarajan *et al.* (PNAS, vol. 89, pp. 8874-8878) **or** Du *et al.* (Direct submission to GenBank, accession no. S53396).

Claim 1 is directed to a purified peptide **comprising** the amino acid sequence selected from the group consisting of SEQ ID Nos:71, 73, 77 and 83, among several others. No upper size limit is specified for the peptides. Claim 17 is directed to producing the polypeptides of interest by expressing polynucleotides.

Glaser *et al.* disclose nucleic acid and hypothetical amino acid sequences which contain the instant SEQ ID NO:71 (the relevant nucleic acid sequence was submitted to GenBank under accession no. S39696). The reference differs from the instant invention in not actually expressing

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the nucleic acid, but it would have been obvious for one of ordinary skill in the art to have done so because it is the protein that is of ultimately of interest.

Natarajan *et al.* disclose nucleic acid and hypothetical amino acid sequences which contain the instant SEQ ID NO:73 (the relevant nucleic acid sequence was submitted to GenBank under accession no. A46242). The reference differs from the instant invention in not actually expressing the nucleic acid, but it would have been obvious for one of ordinary skill in the art to have done so because it is the protein that is of ultimately of interest.

Du *et al.* disclose nucleic acid and hypothetical amino acid sequences which contain the instant SEQ ID Nos:77 and 83 (the relevant nucleic acid sequences were submitted to GenBank under accession nos. S53396 and Q06163). The reference differs from the instant invention in not actually expressing the nucleic acid, but it would have been obvious for one of ordinary skill in the art to have done so because it is the protein that is of ultimately of interest.

Allowable Subject Matter

Claims 6-12 and 21-26 are allowable because the prior art neither teaches nor suggests the instant telomerase reverse transcriptase (TRT) polypeptides and polynucleotides encoding them; nor does the prior art suggest that polynucleotides having the instantly recited sequences (or portions thereof) could be used to identify polynucleotides encoding telomerase reverse transcriptases in body samples. That is, even where the prior art discloses portions of the instantly recited polynucleotides (portions which would be capable of hybridizing with polynucleotides

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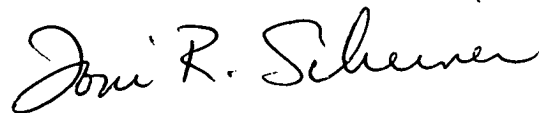
encoding TRT), there is no suggestion that such sequences represent portions of TRT, thus there is no motivation to use the prior art polynucleotides to detect TRT in a sample.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Toni R. Scheiner whose telephone number is (703) 308-3983. The examiner can normally be reached Monday-Friday from 8:30 to 5:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

8/31/98



TONI R. SCHEINER
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GROUP 1600